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SENSITIVE
SIPDIS

DEPT PASS USTR FOR KATHERINE KALUTKIEWICZ AND TANUJA GARDE
DEPT PASS USPTO

E.O. 12958: N/A
TAGS: KIPR ETRD ECON BR
SUBJECT: BRAZIL: PATENT DENIED, GOB PAVES WAY FOR GENERIC PRODUCTION OF IMPORTANT HIV DRUG

¶1. (SBU) SUMMARY: In July, the Brazilian National Institute of Industrial Property (INPI) rejected a patent application by California-based Gilead Sciences for its HIV drug Viread (scientific name: tenofovir). During a trip to Brazil to discuss the case with GOB officials, senior Gilead representatives briefed Econ and Commercial officers on August 6 in Brasilia. The patent rejection (which INPI told Gilead was "purely technical" but accompanied by "lots of pressure" from the Ministry of Health) could be the final step in allowing generic production of tenofovir, since the Ministry of Health (MOH) has already declared tenofovir to be a drug of public interest (April 2008) and established an inter-ministerial group to oversee the development of domestic production capacity (May 2009). More broadly, the decision carries troubling indications for the protection of innovative pharmaceutical products in Brazil. END SUMMARY.

GILEAD TO GOB: DISAGREE, BUT COMITTED TO PATIENT CARE

¶2. (SBU) Gilead intends to file a judicial appeal of the patent rejection in the next 45 to 55 days and will seek an injunction against any applications for generic license. Gilead representatives described their message to the GOB as one of clear disappointment but also continuing commitment to a productive relationship. They characterized meetings with MOH and the National Health Vigilance Agency (ANVISA) as "encouraging" (specifically, the fact that the director of Brazil's AIDS program requested a meeting to discuss supplies of Viread for next year) and showing "good intent."

¶3. (SBU) In Rio de Janeiro, the Gilead team met with the Vice President of INPI and a group of patent examiners. During the meeting, which they described as awkward and tense, they said INPI admitted to being under "lots of pressure" from MOH on the Viread decision. However, according to Gilead, the INPI officials also tried to emphasize that the decision had been "purely technical" and was "consistent with how [INPI] view[s] pharmaceutical patents." (Comment: Post would not have expected MOH to apply pressure directly to INPI, since MOH's own ANVISA would have reviewed the application after INPI, had INPI approved it, and could have independently rejected it (pharmaceutical patent applications must be approved by INPI and then ANVISA before a patent can be issued). This may suggest that MOH fears differing determinations on patentability by INPI and ANVISA could weaken the GOB position in a judicial appeal. End comment.)

"INCREMENTAL INNOVATION" AND SECOND-USE PATENTS

¶4. (SBU) INPI's rejection of the Viread patent claims that the drug

fails to meet the requirement for inventiveness. Gilead counters that many pharmaceutical breakthroughs are based on "incremental innovation" and that the invention of Viread did involve the "inventive step" necessary to qualify for patent protection. Gilead told Emboffs that if INPI is implying opposition to approving patents on incrementally innovative pharmaceuticals, Gilead products and those of other pharmaceutical companies are likely to encounter difficulty in the near future.

¶5. (SBU) The issue of patents for incremental innovation in pharmaceuticals has been the subject of ongoing debate within the GOB. In April 2008, INPI issued preliminary internal guidelines allowing such patents. This decision was criticized by MOH because such patents could prevent the production of generics containing active substances already in the public domain. The Ministry of Foreign Affairs (MRE) was also critical of INPI's guidelines and noted in press reports that the World Trade Organization's Agreement on Trade Related Aspects of Intellectual Property (TRIPS) does not require patent protection for polymorphs or second-use pharmaceutical products.

¶6. (U) In December 2009, the Interministerial Group for Intellectual Property (GIPI)- of which INPI is not a voting member - made an administrative ruling against granting polymorph and second-use patents. Two bills currently before the Brazilian Chamber of Deputies (PL 2511/07 and PL 3995/08) would amend Brazil's intellectual property law to forbid patents for incremental innovations. Both bills remain in Chamber committee and have not reached the floor.

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GILEAD TO USG: SPEAK SOFTLY AND CARRY NO STICK
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¶7. (SBU) In a meeting with Emboffs, Gilead acknowledged that all signs point to generic production of tenofovir. While the company intends to file a judicial appeal, it also wants to continue what it calls a positive relationship with MOH and find a "constructive path forward." Gilead intends to seek new patents in Brazil and says it will not "hold patients hostage" as a result of the Viread patent rejection.

¶8. (SBU) Gilead representatives requested that the USG register disappointment with the GOB regarding the Viread patent rejection and highlight Brazil's position as an "outlier" in this case - every other country where an application was filed has approved the Viread patent. (Note: Gilead said that in meetings with the Brazilian Ministry of Commerce (MDIC) and a patient rights group, interlocutors erroneously believed the U.S. Patent and Trademark Office (USPTO) rejected Viread's patent application in the United States. Although USPTO temporarily suspended the patent (as is standard practice) when a challenge was filed in 2008, the patent was later upheld. End note.) Gilead reps suggested that the arrival of a new Ambassador might afford new opportunities to discuss the case with high-level GOB interlocutors. They repeated, however, that they intend to keep their response positive and non-threatening and that USG engagement should simply convey that the case "has not gone unnoticed."

COMMENT

¶9. (SBU) The Viread decision (and the signs of political pressure applied by MOH) raises new questions about the protection of intellectual property in the pharmaceutical sector in Brazil, where the Health Ministry's apparent "industrial policy" approach to the health care sector has not been countered by other, more pro-IP/pro-innovation voices within GOB. Based on decisions from patent authorities around the world, Viread's scientific case seems strong. INPI's admission of MOH pressure calls into question the "purely technical" nature of this decision and, more broadly, the strength and independence of Brazil's patent regime.

¶10. (SBU) Compulsory licensing has been a topic of much discussion since Brazil's 2007 decision to issue a compulsory license for Merck's HIV drug Stocrin (scientific name: efavirenz) and will continue to be so. However, Brazil's current stance against patents for incremental innovation in pharmaceuticals could have equally damaging results. Political pressure to reject patent applications for legitimately innovative drugs could be a new front in Brazil's push to cut health costs and bolster its generic drug industry, but will ultimately damage innovation and competitiveness. The USG has opportunities to engage on these issues with MRE (through the Economic Partnership Dialogue, the Bilateral Consultative Mechanism, and the Joint Consultative Mechanism[JCM]), MDIC (through the Commercial Dialogue), the Ministry of Science and Technology (which will lead the delegation to the next JCM), and through direct dialogue with the Brazilian Congress. Continuing to press innovation/competitiveness themes and raise their profile within the spectrum of stake-holder agencies will remain an important part of the strategy to affect progress on intellectual property protection in Brazil. END COMMENT.

KUBISKE